REMARKS

Applicant acknowledges receipt of the Office Action mailed December 10, 1997 (paper no. 9). Claims 15-29 are pending, and claims 18, 19, and 25 have been canceled herein without prejudice or disclaimer of matter contained therein. Reconsideration of the rejections and allowance of the claims is respectfully requested in view of the foregoing amendments and the following remarks.

Discussion of Election of Species

In paper no. 5 at pages 2-3, the Examiner required election between the following species:

> Species #1 - method for covering a stent including adhering the stent to a tube using chemical bonding or using curable adhesive or using elastomeric composition disclosed in solvent[; and]
>
> Species #2 - method for covering a stent including removing stent from tube/surface.

By Amendment dated September 5, 1997, applicant affirmed his election of species #1 and added claims 23-29 which depend from the claims of species #1. None of claims 23-29 relate to species #2. In other words, none of claims 23-29 relate to a "method for covering a stent including removing stent from tube/ surface."

Support for new claims 23-29 is found throughout the specification as originally filed, such as at page 2, line 20 to page 3, line 1; at page 3, lines 19-28; and in Figures 1 and 2. These specification passages, reproduced below, relate *inter alia* to the methods of species #1 and to the apparatuses thus made:

> To this effect, the stent and methods in accordance with the invention comply with the definitions given in the claims.
>
> In that way, the continuous covering layer is closely bound to the discontinuous structure which it covers and there is definitely no risk of separation therebetween. And even in the case of a strong degradation of the covering layer in course of time, there cannot be any migration of the covering layer with respect to the discontinuous wall of the stent because of the aforesaid intimal interconnection. Furthermore, the liaison of the covering layer with the discontinuous wall of the stent eliminates any delicate, time and skill consuming efforts and allows coating of any kind of discontinuous expandable stent wall. . . .

The wall (1), comprises, on a portion of its length, a covering layer (3) made of an elastomeric biocompatible composition such as, for instance, the elastomeric polymerisable composition described in U.S. Patent No. 5,112,900. The outer face (4) of layer (3) forms a surrounding surface, and layer (3) extends around and inside the discontinuous structure of the stent in order to totally embrace and intimately unite with any material part of the meshed wires (2) which constitute said discontinuous structure.

In an effort to expedite allowance of this application, Applicant has canceled all claims directed to species #2. All remaining claims relate to species #1, namely, a "method for covering a stent including adhering the stent to a tube using chemical bounding or using curable adhesives or using elastomeric compositions disclosed in solvent."

I. Rejection of claims 20-29 under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness (paper no. 9, page 2).

The Examiner alleges that claims 20-22 are indefinite (paper no. 9, page 2, line 1). However a specific rejection has not been set forth. Applicant respectfully submits that claims 20-22 comply with 35 U.S.C. § 112, second paragraph.

Claims 23, 24 and 26-29 have been amended to provide the antecedent bases required by the Examiner.

Claims 25 has been canceled without prejudice or disclaimer.

Claims 23-29 are alleged to be indefinite for being directed to a non-elected species. However, as discussed above, these claims relate solely to elected species #1 as described throughout the specification, e.g., at page 2, line 20 to page 3, line 1; at page 3, lines 19-28; and in Figures 1 and 2. In any event, 35 U.S.C. § 112, second paragraph, would provide no basis for rejecting claims even if drawn to non-elected species.

In view of the foregoing, applicant respectfully requests that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

II. Rejection of claims 15-17 and 20-29 under 35 U.S.C. § 112, first paragraph (paper No. 9, pages 2-4).

Claims 15-17 and 20-22 have been rejected for allegedly failing to have sufficient support in the specification for the recitation "radially expanding" the stent. However, support for "radially expanding at least the portion of the stent in the tube" is found in the specification, *inter alia*, at page 2, line 33 to page 3, line 1 ("...allows coating of any kind of discontinuous *expandable* stent wall"); at page 5, lines 2-5 ("...the invention is not limited to the embodiment shown, being applicable to any kind of *expandable* stent having a discontinuous wall"); and at page 6, line 27 ("...whereby after expansion ..."). One skilled in the art will appreciate that balloon expandable stents may be expanded by balloons.

Further, the specification as a whole reasonably conveys to one skilled in the art that the inventor at the time the application was filed had possession of the claimed invention. The term "allow" as used by Applicant is defined *inter alia* in *Webster's Third New International Dictionary* (1993), for example, as "permit by way of concession"; "to permit by neglecting to constrain"; "to make a possibility"; and "provide opportunity or basis". Accordingly, the positive recitation of radially expanding at least the portion of the stent in the tube or allowing at least the portion of the stent to expand in the tube is reasonably conveyed by the original specification and one having ordinary skill in the art would have knowledge that a stent may be expanded by, for example, balloons. Thus, the above definitions support both radially expanding at least the portion of the stent in the tube or allowing at least the portion of the stent to expand in the tube.

It is well settled that the specification need only be reasonable with respect to the art involved. Applicant "need not inform the layman nor disclose what the skilled already possess. [Applicant] need not describe the conventional. . . . The intricacies need not be detailed ad absurdum." *General Electric Co. v. Brenner*, 159 USPQ 335, 337 (D.C. Cir. 1968). In addition, "[a]dequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. . . . Rather, it is sufficient if the originally-filed

disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed. *Ex parte Parks*, 30 USPQ 2d 1234, 1236B37 (B.P.A.I. 1993).

Claims 23-29 have also been rejected as allegedly presenting a combination of species #1 and species #2. However, as discussed above, the claims are directed solely to species #1, and support for the claims is found throughout the specification, e.g., at page 2, line 20 to page 3, line 1; at page 3, lines 19-28; and in Figures 1 and 2.

In view of the foregoing, applicant respectfully requests that the rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

III. Rejection of claims 23, 24 and 26-29 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement (paper No. 9, pages 4-5).

As discussed above, Applicant's specification presents a clear enabling teaching regarding claims 23, 24 and 26-29 at page 2, line 20 to page 3, line 1; at page 3, lines 19-28; and in Figures 1-2.

Accordingly, applicant respectfully requests that the rejections under 35 U.S.C. § 112, first paragraph, be withdrawn.

IV. Rejection of claims 15-17 and 20-29 under 35 U.S.C. § 103(a) for alleged obviousness (paper No. 9, pages 5-8).

Applicant's invention relates to a method for covering a stent. Each claim includes steps relating to the pre-forming of a polymeric tube, placing a stent into the tube, then radially expanding the stent or allowing the stent to expand in the tube. The cover is attached to the stent by chemically bonding (claims 15, 20, 23 and 27); curing adhesive medium (claims 16, 21, 24 and 28); or polymerizing an elastomeric composition (claims 17, 22, 25, 26 and 29).

The Examiner has not established a *prima facie* case of obviousness for the following reasons:

(A) **The Rejections Rely Upon Impermissible "Picking and Choosing"**

The Examiner's rejections rely upon a combination of isolated statements from the prior art which have been taken out of context. For instance, it is alleged that MacGregor, at column 1, line 65 to column 2, line 50, teaches the steps of compressing a stent and subsequently expanding a stent. However, MacGregor's teachings relate to the compressing a stent to load it into a catheter for delivery and subsequently expanding the stent from the delivery device into a body vessel. These statements relate to a method of using an uncovered stent, and not to a method of making a covered stent.

It is worth noting that MacGregor's uncovered stent, once expanded in the body vessel in its intended use, is incapable of being covered by subsequent manufacturing steps. Further, as discussed in section (B) below, MacGregor's disclosure is limited to an uncovered stent having an "open architecture" which becomes integrated in a body vessel.

The Examiner also points to "bonding" recitations in MacGregor. But these recitations relate to the bonding of stent elements to each other, and do not relate to the bonding of a stent to a cover: "The present invention may include bonding points **34** *where one portion of the strand engages another portion thereof and at which the strand material is bonded to itself.* ... Bonding may be accomplished in a variety of ways. Thermal bonding may be achieved by drawing and laying down the *strand* . . . Adhesive, which may be biocompatible and hemocompatible, may also be used for bonding purposes." Column 5, lines 8-37. Thus, these recitations should not be relied upon to reject the claims.

The Examiner also points to recitations of "coating." However, these recitations relate to providing biocompatibility for MacGregor's stent, and not for covering a stent with a preformed tube.

Thus, the obviousness rejection relies upon recitations concerning an uncovered stent which is loaded in a catheter and subsequently deployed (still uncovered) in a body lumen wherein the stent elements are bonded to one another (and not a cover) and coated

for biocompatibility and hemocompatibility (while maintaining an open architecture). These recitations are combined to arrive at applicant's method of making a stent covered by a preformed tube. However the Examiner's combination violates the clear standard established by the Federal Circuit against hindsight reconstruction:

> It is permissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'

In re Fritch, 972 F.2d 1260, 23 USPQ 2d 1780 (Fed. Cir. 1992) (quoting In re Fine, 837 F.2d 1071, 1075, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988)).

Applicant respectfully submits that the rejection as presented relies heavily on impermissible hindsight. Accordingly, it is requested that the rejection be withdrawn.

(B) Primary Reference MacGregor (U.S. Patent No. 5,015,253) teaches away from a covered stent

According to MacGregor:

> Because of the *open architecture* of the external surface of the stent **21**, the endothelial tissue of the blood vessel or other hollow organ is not destroyed during a dilation procedure. Furthermore, the patches of endothelium which may be present *in the pores of the stent* **21** will facilitate the quick integration of the stent **21** into the wall of blood vessel or the like.

U.S. Patent No. 5,015,253, column 5, lines 44-50, emphasis added. Thus, MacGregor teaches that his stent has an open architecture which allows it to function by integrating into the wall of a blood vessel. Therefor, MacGregor teaches away from a stent with a covering, as such a covering would destroy the integration function of MacGregor's stent. One skilled in the art would not combine the uncovered stent of MacGregor with secondary documents to obtain a covered stent and thereby defeat the function of MacGregor's stent.

(C) Kaster (U.S. Patent No. 4,441,215) Does Not Suggest Combination with an Expandable Stent

Kaster relates to a vascular graft having two layers. It does not suggest a combination of a stent and a covering. More importantly, it does not suggest radially expanding an inner layer or allowing an inner layer to expand as part of its manufacture. Thus, there is no teaching or suggestion to combine Kaster with the other cited documents.

(D) Simon et al. (U.S. Patent No. 5,354,308) Does Not Suggest Bonding a Preformed Sleeve

Simon et al. purportedly discloses a stent having an elastomeric sleeve. However, as shown at Col. 4, lines 28-47, Simon et al. does not teach or suggest bonding a preformed tube to a stent. Accordingly, it should not be combined with the other cited documents to reject applicant's claims.

REQUEST FOR EXAMINER'S AFFIDAVIT UNDER 37 C.F.R. § 1.107(b)

In paper no. 9, at page 7, line 15 to page 8, line 3, the Examiner alleges the following:

> As to the type of bonding in claims 16 and 21, it would have been obvious to one of ordinary skill in the art to bond using a 'curable adhesive medium' [because] it is taken as well known/conventional in the bonding art to bond a first tubular member to another tubular member by coating the inside of the first tubular member with adhesive and then to insert the second tubular member into the first tubular member ... '[C]urable adhesive medium', which is cured to effect bonding, is taken as a well known/conventional type of adhesive in the bonding art.

In addition, in paper no. 9, at page 8, lines 4-15, the Examiner alleges the following:

> As to the type of bonding in claims 17 and 22, it would have been obvious to one of ordinary skill in the art to bond using 'elastomeric composition dissolved in solvent' [because] it is taken as well known/conventional in the bonding art to bond a first tubular member to another tubular member by coating the inside of the first tubular member with adhesive and then to insert the second tubular member into the first tubular member ... '[E]lastomeric composition dissolved in solvent', which has the solvent evaporized and the elastomer composition polymerized is taken as a well known/conventional type of adhesive in the bonding art.

The foregoing passages essentially allege that most of the steps of the present invention are known or conventional and further implies that such steps are known in a combination which corresponds to the claimed invention. Applicant emphatically disagrees, and respectfully requests that the Examiner provide specific support for these general allegations by way of an Affidavit under 37 CFR § 1.107(b).

In view of the foregoing, applicant respectfully submits that the claims are in condition for allowance. Such favorable action is earnestly solicited.

Respectfully submitted,

Dated: March 9, 1998

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